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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,870	04/17/2006	Robin Paul Martin	SMNPH.006APC	3836

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EXAMINER

TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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09/25/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/575,870	Applicant(s) MARTIN, ROBIN PAUL	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/2008; 06/26/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-9 are amended.
2. Claims 11-35 are new.
3. Claims 1-35 are examined on the merits.
4. Rejection of claims 7 and 8 has been withdrawn based on the amendment made to the claims.
5. Allowable subject matter has been withdrawn in the light of new grounds of rejection over WO 2004/037334.

Response to Arguments

6. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3761

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blott et al. WO 2004/037334 (for convenience the text from the analogue US 7,524,315 has been used) in view of Orgill *et al.* (WO 02/092783 A2).
10. In Re claims 1-4, 19-21 and 32-34, Blott discloses An apparatus for aspirating, irrigating and/or cleansing wounds, comprising:
 - a fluid flowpath, comprising:
 - a conformable wound dressing, having a backing layer capable of forming a relatively fluid-tight seal or closure over a wound, the backing layer comprising a wound-facing face,
 - at least one inlet conduit for moving a fluid to the wound, wherein the at least one inlet conduit is connected to the flowpath and passes through or under the wound facing face of the backing layer,
 - at least one outlet conduit for moving the fluid from the wound, wherein the at least one outlet conduit is connected to the flowpath and passes through or under the wound-facing face of the backing layer,
 - the backing layer forming a relatively fluid-tight seal or closure at the at least one inlet conduit and the at least one outlet conduit, and
 - means for fluid cleansing communicating to the at least one inlet conduit and the at least one outlet conduit adapted to remove from the fluid in the flow path one or more materials deleterious to wound healing;
 - a fluid reservoir switchably connected to the flowpath via means for flow switching in the flowpath between supply of a fluid from the fluid reservoir, recirculation of the fluid in the

Art Unit: 3761

flowpath, and a combination of the supply and the recirculation, wherein the fluid in the flowpath comprises an exudate from the wound or the fluid from the fluid reservoir, or a combination thereof;

a device for moving the fluid through the flowpath; and

means for bleeding the flowpath, adapted to be regulated such that the fluid may be supplied to fill the flowpath from the fluid reservoir via the means for flow switching, or such that the fluid may be recirculated by the device through the flowpath, or the combination of the supply and recirculation (See Col. 44, lines 66-67; Col. 45, lines 1-35);

a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe (See Col. 4, lines 28-37).

Blott does not expressly disclose a biodegradable scaffold located under the backing layer in contact with the wound bed.

Orgill teaches the apparatus for aspirating, irrigating and/or cleansing wounds comprising a biodegradable scaffold 105 (page 8, [0034]; Fig. 8A) located under the backing layer and configured to be placed in contact with a wound bed, wherein the scaffold is being a sponge (claims 2, 19 and 32) ([0062]) and comprises collagen or polyglucolic acid (claims 3, 4, 20, 21, 33 and 34) ([0033] and [0034]).

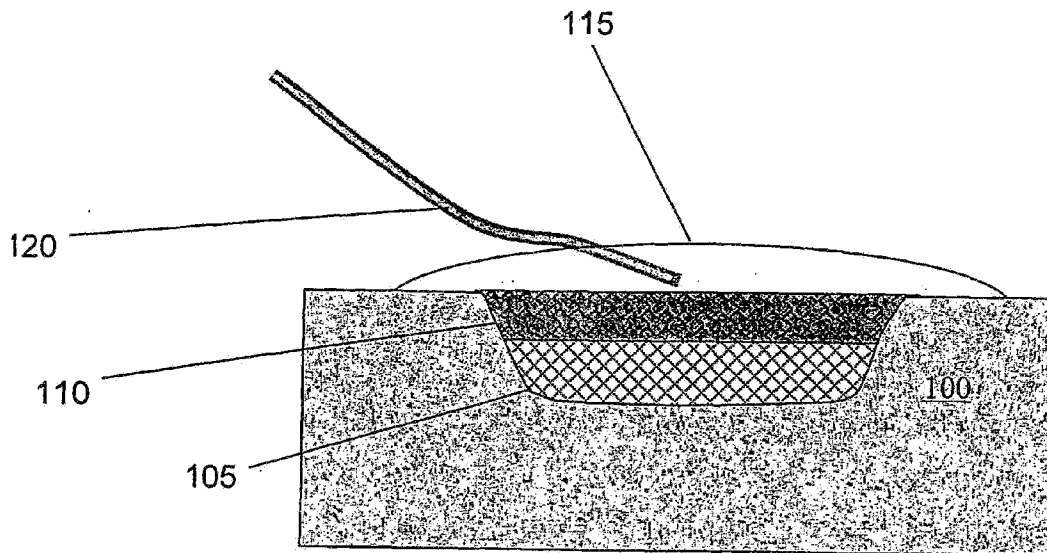


FIG. 8A

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Blott with the biodegradable scaffold, as taught by Orgill in order to utilize the conventionally known material to allow transmission of optimal MicMFs (Orgill, [0009], lines 26-27).

11. In Re claims 5, 14 and 27, Blott discloses the apparatus comprising a means for fluid cleansing that is a single-phase system (Col. 46, lines 19-20).

12. In Re claims 6, 17 and 30, Blott discloses An apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

a fluid flowpath, comprising:

a conformable wound dressing, having a backing layer capable of forming a relatively fluid-tight seal or closure over a wound, the backing layer comprising a wound-facing face,

Art Unit: 3761

at least one inlet conduit for moving a fluid to the wound, wherein the at least one inlet conduit is connected to the flowpath and passes through or under the wound facing face of the backing layer,

at least one outlet conduit for moving the fluid from the wound, wherein the at least one outlet conduit is connected to the flowpath and passes through or under the wound-facing face of the backing layer,

the backing layer forming a relatively fluid-tight seal or closure at the at least one inlet conduit and the at least one outlet conduit, and

means for fluid cleansing that is a two-phase system (claims 17 and 30) (Col. 46, lines 19-21) communicating to the at least one inlet conduit and the at least one outlet conduit adapted to remove from the fluid in the flow path one or more materials deleterious to wound healing;

a fluid reservoir switchably connected to the flowpath via means for flow switching in the flowpath between supply of a fluid from the fluid reservoir, recirculation of the fluid in the flowpath, and a combination of the supply and the recirculation, wherein the fluid in the flowpath comprises an exudate from the wound or the fluid from the fluid reservoir, or a combination thereof;

a device for moving the fluid through the flowpath; and

means for bleeding the flowpath, adapted to be regulated such that the fluid may be supplied to fill the flowpath from the fluid reservoir via the means for flow switching, or such that the fluid may be recirculated by the device through the flowpath, or the combination of the supply and recirculation (See Col. 44, lines 66-67; Col. 45, lines 1-35);

a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe (See Col. 4, lines 28-37).

Blott does not expressly disclose a biodegradable scaffold located under the backing layer in contact with the wound bed.

Orgill teaches the apparatus for aspirating, irrigating and/or cleansing wounds comprising a biodegradable scaffold 105 (page 8, [0034]; Fig. 8A) located under the backing layer and configured to be placed in contact with a wound bed.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

13. In Re claim 7, Blott discloses the apparatus wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable to materials deleterious to wound healing (Col. 44, lines 13-19).

14. In Re claim 8, Blott discloses the apparatus wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is not selectively permeable to materials deleterious to wound healing, and the other fluid comprises and/or is in contact with a material that removes materials deleterious to wound healing (Col. 44, lines 19-27).

15. In Re claim 10, claim 10 is a product-by-process claim, and since the claimed product is fully disclosed by the combination of references, the method of treating wounds imbedded in the claim does not impact patentability to the claim.

16. In Re claims 11 and 24, Blott discloses the apparatus wherein at least a portion of the fluid flowing through the outlet pipe is directed to a waste reservoir (Col. 3, lines 64-67).

Art Unit: 3761

17. In Re claim 12, Blott discloses the apparatus wherein the means for fluid cleansing comprises a biphasic extraction unit (Col. 4, lines 25-27).

18. In Re claim 13, Blott discloses An apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

a fluid flowpath, comprising:

a conformable wound dressing, having a backing layer capable of forming a relatively fluid-tight seal or closure over a wound, the backing layer comprising a wound-facing face,

at least one inlet conduit for moving a fluid to the wound, wherein the at least one inlet conduit is connected to the flowpath and passes through or under the wound facing face of the backing layer,

at least one outlet conduit for moving the fluid from the wound, wherein the at least one outlet conduit is connected to the flowpath and passes through or under the wound-facing face of the backing layer,

the backing layer forming a relatively fluid-tight seal or closure at the at least one inlet conduit and the at least one outlet conduit, and

means for fluid cleansing communicating to the at least one inlet conduit and the at least one outlet conduit adapted to remove from the fluid in the flow path one or more materials deleterious to wound healing;

a fluid reservoir switchably connected to the flowpath via means for flow switching in the flowpath between supply of a fluid from the fluid reservoir, recirculation of the fluid in the flowpath, and a combination of the supply and the recirculation, wherein the fluid in the

Art Unit: 3761

flowpath comprises an exudate from the wound or the fluid from the fluid reservoir, or a combination thereof;

a device for moving the fluid through the flowpath (See Col. 44, lines 66-67; Col. 45, lines 1-35);

a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe (See Col. 4, lines 28-37).

Blott does not expressly disclose a biodegradable scaffold located under the backing layer in contact with the wound bed.

Orgill teaches the apparatus for aspirating, irrigating and/or cleansing wounds comprising a biodegradable scaffold 105 (page 8, [0034]; Fig. 8A) located under the backing layer and configured to be placed in contact with a wound bed.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

19. In Re claims 15 and 28, Blott discloses the apparatus wherein the fluid cleansing mechanism comprises an ultrafiltration unit (Col. 46, line 21).

20. In Re claims 16 and 29, Blott discloses the apparatus wherein the fluid cleansing mechanism comprises a chemical absorption and/or adsorption unit (Col. 18, lines 1-2).

21. In Re claims 18 and 31, Blott discloses the apparatus wherein the fluid cleansing mechanism comprises a dialysis unit (Col. 46, lines 19-23).

22. In Re claims 22 and 35, Blott discloses the apparatus comprising means for bleeding the fluid flow path to bleed fluid from the recirculation tube (See Col. 4, lines 28-37).

Art Unit: 3761

23. In Re claim 23, since the apparatus of Blott is disclosed as provided for aspirating, irrigating and/or cleansing wounds, Blott discloses the method of treating a wound comprising:

- providing a conformable wound dressing configured to form a relatively fluid- tight seal around at least a portion of a wound;
- providing an apparatus for irrigating and/or cleansing a wound comprising: a fluid reservoir comprising irrigation fluid;
- at least one inlet pipe configured to communicate with the dressing and to provide a fluid conduit into the dressing;
- at least one outlet pipe configured to communicate with the dressing and to provide a fluid conduit out of the dressing;
- pumping fluid through at least the inlet pipe, the wound dressing, and the outlet pipe;
- cleansing the fluid that flows out of the wound dressing to reduce the amount of deleterious components in the fluid that flows out of the dressing without substantially reducing the amount of the components in the fluid that flows out of the dressing that are beneficial to wound healing; and
- recirculating at least a portion of the fluid that flows out of the wound dressing back to the dressing after being cleansed so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound (See Col. 4, lines 28-37; Col. 44, lines 66-67; Col. 45, lines 1-35).

Blott does not expressly disclose positioning a biodegradable scaffold under the dressing, wherein at least a portion of the scaffold is in contact with the wound bed.

Orgill teaches the method comprising positioning a biodegradable scaffold under the dressing, wherein at least a portion of the scaffold is in contact with the wound bed (page 8, [0034]; Fig. 8A).

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

24. In Re claim 25, Blott discloses the method comprising adjusting the proportion of the amount of fluid that is provided to the dressing after being cleansed and the amount of fluid provided to the dressing from the fluid reservoir (Col. 5, lines 13-17).

25. In Re claim 26, Blott discloses the method wherein cleansing the fluid comprises at least reducing the amount of fluid soluble deleterious components in the fluid that flows out of the dressing (See Col. 43, lines 66-67; Col. 44, lines 1-5).

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3761

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761